

# Attachment B

## how to read a drug label

1 Who

specific about your pain.

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Most over-the-counter medicines have a Drug Facts label to help you select the right product and use it correctly.

Roll over the numbers on the sample label below for a detailed explanation.

1	<b>Drug Facts</b> <b>Active ingredient (in each caplet)</b> Ibuprofen 200 mg (NSAID) *nonsteroidal anti-inflammatory drug	<b>Purpose</b> Pain reliever/ fever reducer				
2	<b>Uses</b> ■ temporarily relieves minor aches and pains due to: ■ headache                      ■ muscle aches ■ minor pain of arthritis    ■ toothache ■ backache                    ■ the common cold ■ menstrual cramps ■ temporarily reduces fever					
3	<b>Warnings</b> <b>Allergy alert:</b> Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives                              ■ facial swelling ■ asthma (wheezing)           ■ shock ■ skin redness/itching         ■ rash ■ blisters ■ an allergic reaction occurs, stop use and seek medical help right away. <b>Stomach bleeding warning:</b> This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while ■ take more or for a longer time than directed <b>Do not use</b> ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery <b>Ask a doctor before use if you have</b> ■ problems or serious side effects from taking pain relievers or fever reducers ■ stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain ■ ulcers ■ bleeding problems ■ high blood pressure ■ heart or kidney disease ■ taken a diuretic ■ reached age 60 or older <b>Ask a doctor or pharmacist before use if you are</b> ■ taking any other drug containing an NSAID (prescription or nonprescription) ■ taking a blood thinning (anticoagulant) or steroid drug ■ under a doctor's care for any serious condition ■ taking any other drug					
	<b>Drug Facts (continued)</b> <b>When using this product</b> ■ take with food or milk if stomach upset occurs ■ long term continuous use may increase the risk of heart attack or stroke <b>Stop use and ask a doctor if</b> ■ you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding. ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms appear <b>If pregnant or breast-feeding, ask a health professional before use.</b> It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)					
4	<b>Directions</b> ■ do not take more than directed ■ the smallest effective dose should be used ■ do not take longer than 10 days, unless directed by a doctor (see Warnings) <table border="1"> <tr> <td data-bbox="719 1371 812 1507">adults and children 12 years and older</td> <td data-bbox="820 1371 1102 1507">           ■ take 1 caplet every 4 to 6 hours while symptoms persist            ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used            ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor            ■ ask a doctor         </td> </tr> <tr> <td data-bbox="719 1518 812 1633">children under 12 years</td> <td data-bbox="820 1518 1102 1633"></td> </tr> </table>		adults and children 12 years and older	■ take 1 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor ■ ask a doctor	children under 12 years	
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children under 12 years						
5	<b>Other information</b> ■ store between 20 - 25°C (68 - 77°F) ■ do not use if neck wrap or foil inner seal imprinted "Safety Sealer" is broken or missing ■ see end panel for lot number and expiration date					
6	<b>Inactive ingredients</b> carnauba wax, corn starch, FD&C yellow #6, hypromellose, iron oxide, polydextrose, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide					
7	<b>Questions or comments?</b> Call 1-877-893-3663 (English) or 1-888-486-8746 (Spanish) weekdays 9:00 AM to 4:30 PM EST					



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Advil The Every Pain

## About New Advil® Labeling

- ☐ Advil Home
- ☐ Adult Products
  - ☐ Advil
  - ☐ Advil PM
  - ☐ Advil Migraine
  - ☐ Advil Cold & Sinus
  - ☐ Advil Allergy Sinus
  - ☐ Advil Multi-Symptom Cold
- ☐ Children's Products
- ☐ Pain Free Living
- ☐ FAQ
- ☐ Buy Online
- ☐ Find A Store Near You
- ☐ Wyeth Special Offers

This is the most current labeling information, and may differ from labels on product packaging. If there are any differences between this website labeling and product package labeling, this website labeling should be regarded as the most current.

The FDA has approved enhanced warning labels for all over the counter non-steroidal anti-inflammatory drug analgesics (NSAID), including all Advil® products. These new labels will provide consumers with more information about potential cardiovascular, gastrointestinal and allergic risks.

Products with revised labels should be in stores by late 2006. In the meantime, we have posted the revised label on this Web site. We continue to work with the FDA to ensure the effective labeling of our products.

Wyeth Consumer Healthcare stands firmly behind the safety and effectiveness of Advil®. However, we encourage all consumers to read the new, enhanced Advil® labeling, with special attention to the Warnings. All drugs, including those without a prescription, must be used according to their directions to be safe and effective.

## Advil® Liqui-Gels®

### Drug Facts

#### Active Ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)

(present as the free acid and potassium salt)

\*nonsteroidal anti-inflammatory drug

#### Purpose

Pain reliever/Fever reducer

### Uses

temporarily relieves minor aches and pains due to:

headache      toothache      backache      menstrual cramps  
the common cold      muscular aches      minor pain of arthritis

temporarily reduces fever

### Warnings

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

hives      facial swelling      asthma (wheezing)  
shock      skin reddening      rash      blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is

higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Do not use**

If you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery

**Ask a doctor before use if you have**

- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- high blood pressure
- heart or kidney disease
- taken a diuretic
- reached age 60 or older

**Ask a doctor or pharmacist before use if you are**

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

**Stop use and ask a doctor if**

- you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not take more than directed**
- the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

**Other information**

- each capsule contains:** potassium 20 mg
- read all warnings and directions before use. Keep carton.

store at 20-25°C (68-77°F)  
avoid excessive heat above 40°C (104°F)

**Inactive ingredients**

FD&C green no. 3, gelatin, light mineral oil, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitans, sorbitol

Questions or comments? call toll-free 1-800-88-ADVIL

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This site is intended for residents of the [United States](#).

## Attachment D

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CENTRAL FAX CENTER

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## Upper level

Acesulfame K

Aspartame

Calcium chloride

Erythorbic acid

DL-Lactic acid

L-Lactic acid

Potassium sorbate

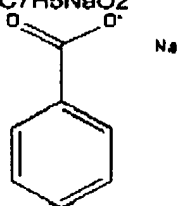
Sodium benzoate

Sodium erythorbate

Sorbic acid

## Sodium Benzoate

## Identification

**Synonyms:** Isoascorbic Acid Sodium Salt; Sodium Isoascorbate**CAS No.:** 532-32-1**Molecular Weight:** 144.10**Molecular Formula:** C<sub>7</sub>H<sub>5</sub>NaO<sub>2</sub>**Structural Formula:**

## Application

sodium benzoate is applied as an antioxidant used in meat, poultry, soft drink.

## Specification

Complied with BP98/FCC IV, Kosher Certified

Item	Specification
sodium benzoate purity	99.0%min.
moisture	1.5% max.
chlorides as Cl	200ppm max.
total chlorides	300ppm max.
heavy metals as Pb	0.001% max.
arsenic as As	0.0003% max.
alkalinity	0.2ml/g max.
color of solution	Y6
appearance	white crystalline powder or granule

## Standard Packing

25kgs net/woven bags with plastic inner bags, or Kraft bag

## Risks and Safety Info

Safe for land, air and water transportation

## Availability

## Attachment E

Ibuprofen was made available under prescription in the United Kingdom in 1969, and in the United States in 1974. In the years since, the good tolerability profile along with extensive experience in the community (otherwise known as Phase IV trials), has resulted in the rescheduling of small packs of ibuprofen to allow availability over-the-counter in pharmacies worldwide, and indeed in supermarkets and other general retailers. For some time, there has been a limit on the amount that can be bought over the counter in a single transaction in the UK; this being 2 packs of 16 x 200 mg or 1 pack of 8 or 16 x 400 mg, the latter being far less common for over-the-counter sales. In the United States, the Food and Drug Administration approved it for over-the-counter use in 1984. The wider availability has meant that ibuprofen is now almost as commonly used as aspirin and paracetamol (acetaminophen).<sup>[citation needed]</sup> In other countries, such as Spain, higher dosages of 600 mg are available. Mexico's doses go up to 800mg per pill.